HIT Standards Committee
Final Transcript
August 15, 2012

Presentation

Operator

All lines are now bridged.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Operator, good morning. This is Mary Jo Deering in the Office of the National Coordinator for Health IT and this is the 39th meeting of the Health IT Standards Committee. It is an open public meeting and there will be an opportunity for the public to make comments at the end and I would remind the members to identify themselves when they are speaking for the transcript and for the people listening. I'll begin by taking the roll. Jon Perlin?

Jonathan Perlin – Hospital Corporation of America

Good morning.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

John Halamka?

John Halamka – Harvard Medical School

Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Dixie Baker?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I'm here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Anne Castro?

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

I'm here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Chris Chute?

Christopher Chute – Mayo Clinic College of Medicine

Present.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Tim Cromwell? Carol Diamond? Lorraine Doo?

Lorraine Doo – Centers for Medicare & Medicaid Services – Senior Policy Advisor
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Floyd Eisenberg? Jamie Ferguson?

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Martin Harris?

C. Martin Harris - Cleveland Clinic Foundation
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Stan Huff?

Stanley M. Huff - Intermountain Healthcare
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Kevin Hutchinson? Liz Johnson?

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Rebecca Kush?

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Arien Malec? David McCallie?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Nancy Orvis? Marc Overhage?

Marc Overhage – Siemens Corporation
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Wes Rishel?

Wes Rishel – Gartner, Incorporated
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Chuck Romine?

Kamie Roberts – National Institute of Standards and Technology – Associate Director
This is Kamie Roberts for Chuck.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Thank you Kamie. Cris Ross? Walter Suarez?

Walter Suarez – Kaiser Permanente
Good morning; I'm here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Sharon Terry?

Sharon Terry – Genetic Alliance – President and CEO
I'm here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Jim Walker?

Jim Walker – Geisinger Health System – Chief Information Officer
Here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Okay, would staff on the line please identify themselves?

John Derr – Golden Living, LLC
Mary Jo, it's John Derr. I didn't hear my name; I'm here.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology
Oh, John, yes I did call it earlier, thanks very much, John. Any other members who I missed? Okay, would staff identify themselves, please?

MacKenzie Robertson – Office of the National Coordinator
MacKenzie Robertson, ONC.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Okay, back to you, Jon.

Jonathan Perlin – Hospital Corporation of America

Well, good morning everybody and thank you so much for joining today's call, you know, in many ways a virtual meeting is tougher than an in person meeting, in person, despite the challenges of travel, the focus is really on the task at hand. So, let me thank you because I know when you don't travel you're not away from desks and all of the other obligations of your daily role. So, appreciate very much your attention and participation particularly for those of you further west for whom it is very early.

I just note, this is such an interesting time it's interesting in the sort of lifecycle of the year, it's the time where the schools are beginning again both the universities and here in the south the grade schools as well. It's a time then that also takes the cycle of businesses to considering their strategies for the upcoming year; in fact their budget planning was really in that context. I was part of large group in a New York study yesterday and apropos of our work what was so fascinating was not the question being debated, will we have health information, not even when will we have health information but really with full recognition of the work that you've been so much a part of.

The question was really how will we use this information to greatest effect. What is the return from information liquidity and that liquidity is really thinking about the mobility of information of course in all of the appropriate private and secure ways that we help to shepherd, but also the capacity for that information to support patients across time and geography, support teams across circumstances and increasingly for that ecosystem to expand beyond even what we have really set as our primary focus but to include all of information coming from mobile devices and environmental reports, and patient reported, and observer reported information that in aggregate really will form a much more robust learning environment and that's really something to be very excited about.

And, I didn't mention that the conversation was also replete with a discussion of all the various levels of…and so we're really at the cusp of the new ecosystem and I hope you feel as excited about that but also rightfully proud because it has really been so much of your work to ONC, your work on leadership that we can have discussions of the sort that are occurring.

That's really by way of segue into today's agenda because we begin to, not only push forward in terms of some final comments in the Implementation Workgroup with some concerns about making sure that our infrastructure for information liquidity, our infrastructure for information production is supported by timelines that allow the community of really enthusiastic participants, vendors, providers, payers, patients alike to be able to have the right systems in place to be able to not only create information in their environments but to really support that liquidity of information that's the greater aspiration.

And then a little bit out of chronology for this morning then just such an important discussion that Dixie and team will be leading on the recommendations, final report on criteria to assess maturity of specifications and standards, and I particularly appreciate the work that this group has done both in terms of using the product that they've developed but in terms of developing a coherent framework for assessment of the readiness of standards to support the intended use.

Jim Walker has informed us that he really would like to foster more of a dialogue about some of the recommendations and the value set repository and look forward to that discussion as well as giving Doug Fridsma adequate time to really discuss some of the current and future direction in ONC and I know that in the really robust agendas of the past meetings we've shortchanged him a little bit, so we look forward to that.

I do know that we're scheduled to 1:00 and, you know, of course we'll, you know, give every topic as much time for discussion as we possibly can, but it's also not inconceivable that if we're efficient in our discussions that we may complete our responsibilities even before the anointed hour but we'll play that out as the discussions and your interest dictate.

Let me, before I turn to John Halamka for his comments, perhaps then just a direct lead into the first topic of discussion, let me just ask if everyone had a chance to review the minute and if anyone has any amendments, amplifications, corrections. So take a moment and I'll ask for your consensus momentarily.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Jon, this is Dixie, I have a slight typo.

Jonathan Perlin – Hospital Corporation of America

Please identify?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Page 4, I'm identified as Banker instead of Baker. I wish I were, but I'm…actually, I think they've done a good job of capturing everything else.

Jonathan Perlin – Hospital Corporation of America

Okay, terrific, we will rename you Baker as opposed to Banker, but thank you. Any other corrections? Hearing none in the absence of objections we'll declare consensus on the minutes and let me then turn over to Dr. John Halamka. Good morning, John, if you would both offer your overview comments and if you would just lead us right into the NwHIN Power Team Report.

John Halamka – Harvard Medical School

Oh, absolutely, thanks and good morning everybody. Jon Perlin framed it well about the time of history we are living in right now. If you think about where we are in this whole cycle of meaningful use we are just on the cusp of getting the Meaningful Use Stage 2 final regulations. I don't think on today's call we're going to hear exactly the timing of that but of course there is much discussion in the industry that is impending and of course as Jon has said, Liz Johnson's letter and the Implementation Workgroup activity emphasizing the importance of moving that forward in a timely manner is something we will discuss today.

But, if we assume in the next few weeks that Meaningful Use Stage 2 or the 2014 addition will become that final rule we all can see our next tranche of work is the certification process to make sure that the testing and certification criteria and processes are very robust because as so many folks in the Standards Committee have expressed for this time in history, here we are finishing Stage 1, starting ICD-10 and we have these timelines that are extraordinarily compressed for Stage 2 where we don't yet have a final regulation and we don't yet know all the certification and testing criteria that we will all have to adhere to, to be into full production everywhere with everything by October 1 of 2013.

So, I think, we as a committee just need to be absolutely focused on getting all of this to the public, to the vendors, to the providers in a very timely manner and making sure the testing and certification criteria and processes are very robust. So, with Doug's conversation, the Q&A which will take place in the latter part of our meeting I certainly look forward to making some progress on those fronts.

We are also then going to turn our attention to Stage 3 after we get Stage 2 completely wrapped up. I have had many phone calls and many requests from various subcommittees of the HIT Policy Committee specifically asking "well we would like to do this aspirational clinical workflow in Stage 3, are the standards mature enough to support that?" And of course, this is a very challenging question to answer without robust maturity guidelines as to whether or not a standard is good enough for a particular purpose.

So, again the importance of today's meeting at this time in history is not only will we focus on Stage 2 stage and where we're going with certification and testing, but we will focus on getting those maturity criteria specifically identified and finalized so that when we are asked "gee, if care plans require 17 structured data elements are their mature enough standards to support that or do we have to be somewhat less aspirational in our clinical goals awaiting standard maturity." So important work and certainly look forward to the discussion. So, with that, Dixie, tell us what your group has done on those maturity criteria.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay, thank you very much, John. It is, let me see; can we go ahead and put the slides up? Okay, thank you. Today is the day that the Nationwide Health Information Network Power Team is reporting our final recommendations for standards evaluation criteria. This work, as you know, began last summer and was where we started developing some criteria and attributes having to do with the maturity and adoptability of standards, and specifications, and was reconvened early this year with the task of filling out and further developing, and refining that work. So, do I have control here? Next slide, please.

These are the power team members and I would like to thank all of the members for their participation and I'd also like to thank Avinash Shanbhag and Todd Parnell from ONC for their support on this work. Next slide, please.

This is just reminder of the context of what we're doing here. The diagram at the right of your screen is a slight modification of a diagram that appeared in the governance RFI and what it shows is a matrix showing maturity on the y-axis and adoptability on the x-axis and looking at how a specification might be plotted on this grid such that one could identify it as an emerging standard not quite ready for piloting, a standard that was ready for or a specification that would be ready for piloting but not quite ready to become a national standard or whether it really was both mature and adoptable enough such that it could be specified in a regulation or otherwise as a national standard.

On the left you see, again this is just a reminder, in each of these categories maturity and adoptability we identify three criteria. The maturity criteria are the maturity of a specification itself, the maturity of the underlying technology components that are embedded within that specification and market adoption. The three criteria for adoptability are ease of implementation and deployment, ease of operations, and intellectual property. So, with that, let's move onto our recommendations. Next slide, please, there we go, thank you.

There are three slides here where I will summarize the changes that we've made since I last presented this work to you at the July meeting. And all of the final recommendations are in appendix A and wherever we made a change I've highlighted it in red type, when this ultimately goes to ONC of course we'll get rid of the red type, but that's for your help in seeing where the changes were made. The first of the three slides contains the…identifies four changes or they identify our four responses to topics and suggestions that were brought up at the July meeting.

First you'll recall that Walter Suarez suggested that we incorporate the source of the specification as a metric and so we have added…its association with a voluntary consensus standards body as a metric for breadth of support which is an attribute of the maturity of the specification itself. There was a lot of conversation in our last meeting you'll recall about optionality and how optionality can be both good and bad, and appropriate or inappropriate and it's not really a matter of its degree of optionality but rather its appropriateness, and so we've changed that from the degree of optionality to appropriate optionality as the attribute of ease of implementation and deployment. We did not change any of the metrics because interestingly, the metrics themselves really were addressing the appropriateness of optionality and was more the title of the attribute itself than the real content of the metrics.

The third, the ease of operations criteria, you'll recall that Jamie Ferguson talked about the peer coordination, he brought up some conversation around whether peer coordination, you know, peer coordination is often essential for interoperability he was asserting and we all agreed, and as it turned out, you know, in discussing this further with him we realized that we really needed to clarify that we were talking about degree of peer coordination by technical experts and so we've again changed that title of the attribute to degree of peer coordination by technical experts and clarified it where we needed to in the metrics itself as well.

You'll remember that Jodi Daniel brought up the…whether we had considered the availability of alternatives and we discussed this, and we concluded that this should be something that is considered by ONC prior to and maybe even as part of a request that's given to the specification evaluation team itself, but it shouldn't be an evaluation criterion in and of itself. In other words what we're saying is, you know, before they come up with a specification to be evaluated they should consider whether there are alternatives and perhaps even ask the evaluation team to compare two alternatives, but the availability shouldn't be a measure of…the availability of alternatives shouldn't be a measure of either the maturity or implementability. Okay, next slide, please.

Okay, there was one attribute that was in both maturity specification and maturity of underlying technology, it was called interoperability among a number of independent implementations and according to the metrics that we had listed in that, it really wasn't measuring the maturity of the specification or technology to one, but it was more market adoption and so we've taken it out of both the maturity specification and maturity of technology and we've added in the market adoption...we added to the market adoption criterion an attribute called interoperable implementation which encapsulates and pulls in the same metrics that we previously had in the other two criteria.

We discovered during our Infobutton evaluation exercise that some of the attributes we had named in a way such that they were confusing because you could have a measure of high that would really mean, give it a low score, for example, complexity, high complexity is not a good thing it's a bad thing but, you know, our measures are low, moderate, and high and so it became a little confusing to just respond to these types of things. So we went through the whole set of attributes and metrics and made sure that the attribute names accurately reflected the semantic value of low, moderate and high so that it was more consistent between the attribute name and the low, medium and high ratings that we attributed to them.

Then the final one on this slide, we had two attributes under ease of implementation and deployment whose metrics were very, very similar and their metrics both had to do with specification modularity so we combined them into specification modularity, the second one was complexity of specification and we just pulled those metrics into specification modularity. Next slide.

The maturity…this final change that we made was clearly a direct outcome of our…it was a lessons learned from the Infobutton evaluation exercise, in doing that exercise you recall that we had said that for the majority of the underlying technology components that each technology component should be individually evaluated according to the metrics and the attributes, and we discovered that as we did the exercise that that really wasn't realistic, you know, because in many cases there could be multiple technology components at finer and finer granularity, and it really could make it…it would impose an unrealistic level of complexity, and unnecessary level of complexity there.

So, we changed the metrics to reflect the change in the approach from the separate evaluation of each technology component to a single evaluation of all of the technology, of that set of technology components that were used by the specification and then the evaluator would identify those technologies that contributed to the ratings that they had assigned. Interestingly, when we did the Infobutton exercise, that's really what everybody did and it worked out well so we changed the metrics so that that's the way it works now. Okay, next slide.

Okay, moving onto the evaluation exercise. The Power Team selected the HL7 Infobutton specification to test the usability of the defined metrics and we basically selected this based on…because it is a relatively small specification so we thought it was something that we could do within a, you know, a relatively short period of time and you may recall that during the NPRM review this committee had considerable discussion around the Infobutton standard.

So, at the top, you will see the official references to it. We started off with the context to where retrieval application release one, that is the Infobutton specification and then it has an implementation guide, URL-based implementation of context to where retrieval. We found that because the specification itself doesn't really contain any functionality, it's really an information model, that in order for these metrics to have meaning we needed to include the implementation guide as part of the exercise. So, that was one of the lessons learned as you'll see a specification that is presented for evaluation really needs to include some functionality and so in some cases that may mean including an implementation guide along with the specification itself.

The Infobutton standard aims to facilitate the integration of knowledge resources into clinical systems whether it be for clinicians or for patients, or whomever it allows one to pull in knowledge resources based on the context. And as I mentioned the specification includes only the knowledge request information model. So, the next slide, please.

Our plan was to distribute the specification and the individual evaluation worksheet to evaluators to have the evaluators record their ratings and then submit them to the chair and then the chair would record the ratings on the team consensus evaluation worksheet and then everybody would get together for discussion and to come to consensus on a rating. Now this approach is really based on one that I was exposed to through some work I did to support some evaluations for ONC and it worked out very well to have individual people rate things and then come together as a group, as a team to discuss your impressions and your ratings and to come to a single team consensus, set of team consensus rating.

I would note that I've included both the individual evaluation worksheet and the team consensus evaluation worksheet as part of your materials for this meeting so those are in there and they are drafts, so they may be slightly modified depending on what comes out of today's discussion.

So, what actually happened is that we did provide the Power Team with the specification and the individual worksheet and then, as I mentioned, we discovered we also had to give them the pointer to the implementation guide to enable them to do the functional assessment. Three members submitted their ratings and so to encourage further people to submit ratings I recorded these three…the ratings from these three evaluations on the team consensus worksheet and I sent them out to everybody on the Power Team and I said "okay, here's what we have so far, if you'd like to add anything please do."

And then one of our Power Team members did respond and submitted an additional individual evaluator worksheet and he noted the benefits of seeing the other ratings because in some areas he really wasn't sure he didn't have adequate experience, etcetera. When we actually then came together in the team discussion this same impression was expressed by everybody really that it was very valuable to share their ratings with one another in ultimately reaching the consensus ratings. Okay, next slide.

So, this slide contains consensus ratings for the maturity criteria and appendix B has all of the detailed scores, but I really didn't want to focus on those detailed scores, we really wanted to focus on the exercise itself and the lessons learned from it. So, here I have our consensus ratings, the overall rating on maturity was between low and moderate and the next slide is the adoptability rating and the adoptability consensus rating was moderate, and again, I would refer you to appendix B for the specific ratings that people assigned. Okay, next…we can move onto the lessons learned.

Oh, this is the classification, so going back to our grid you'll see that if…that looking at the Infobutton our assessment of the Infobutton specification and implementation guide, it falls into the pilot realm, you'll recall that we rated it low to moderate in maturity and moderate in adoptability. Next slide.

So, lessons learned, as I've said, the specification package that is presented by ONC to this evaluation team needs to include functions and so if the…many specifications themselves are functional so you could just, you know, hand over the standard specification and say "evaluate this" but in other cases, and Infobutton being one of them, where it really…it's just an information model then you need to include at least one implementation guide as part of the evaluation.

A second lesson learned is the team needs to understand the use cases that the specification is being evaluated for. We had considerable discussion for example on this one as to whether we were looking at it as something to be used for knowledge retrieval for consumers or for clinicians, or for both. So, that needs to be communicated along with the specification itself. And, as I mentioned earlier, we did learn that the attribute names needed to be changed so that low was always bad and high was always good. Okay, next slide.

The original approach, I mentioned earlier, that called for the separate evaluation of the maturity of each technology component in the specification and we discovered that that was really unrealistic and we thought it adds complexity where it really didn't need to add that complexity, but we wanted to emphasize that it's important for this particular criterion to have the evaluators identify the core technology components that influence their ratings so that we know where did you come up with that low, you know, for example in the Infobutton specification it's basically, and the implementation guide, they basically use HTTP, you know, how simple can you get, how adopted, you know, how mature can it be, it's very mature, very widely adopted, but the specification also uses the HL7 version 3 reference information model, which is not quite as widely adopted and is not as mature as HTTP. So, the two together, you know, came up, had to be considered to come up with the maturity of the technology score and both…and it was useful to identify what influenced a score, a rating that was assigned.

The sharing of these ratings and the comments as well, you'll see that the individual worksheet has a field there for comments and sharing those among the evaluators was very helpful because some evaluators, different evaluators had different knowledge levels of different attributes of the specification. So, one of our evaluators suggested, and I think it's a good suggestion, that the evaluation and classification process maybe well suited for a Delphi-like approach wherein the evaluators are asked to assign ratings independently and then the ratings are shared anonymously, and then after that the evaluators might…would reassign ratings and then finally come together for the final consensus, and I think that this would work well for this particular purpose. Next slide, please.

We had a couple of recommendations for the evaluation process. We've said this many, many times but we've also, it has come up many, many times in our discussions. It's really important that the evaluation process…to recognize that the evaluation process and metrics that we're proposing here are intended to provide structure and discipline to what still is a qualitative evaluation and classification of technical specifications, it's not 100% quantifiable and so it's important that these metrics not be used to generate a numeric score that are then averaged across evaluators to determine some minimum score in order to become a national standard, but rather to use the metrics to inform and justify the classification decision and this we feel is very, very important.

We think that ONC, when they select specifications to submit for evaluation, those should be selected based on industry needs for specific use cases. So, industry needs should really drive the decision, but when that specification is presented, they should provide the description of the use cases that they have in mind so that the evaluation team has a context for the evaluation. And if the specification is not a functional specification they should include implementation guidance. And if alternatives exist they should consider asking for a comparative evaluation.

And periodically, this came up at our last Standards meeting you'll recall, that it's important to incorporate some process for identifying national standards, existing national standards that may need to be reevaluated to see if there still should be national standards. Okay, I think that's the end. Next slide I think is the appendix, yes, appendix A are all of the criteria, attributes and metrics and as you'll see they have…I have highlighted the changes using red font and appendix B are the ratings from our Infobutton exercise. And with that, I'm ready to take questions.

John Halamka – Harvard Medical School

Well, great, Dixie, thanks so much. A tour de force as usual and how timely is this, during your presentation Paul Tang sent me a series of questions from the Meaningful Use Workgroup saying "so we need to assess the maturity of several standards and we aren't sure of the process that should be used to do that. And, so, in fact, Mary Jo, I think and Jon Perlin, these questions are probably likely to be assigned to our Clinical Operations Workgroup with some maybe going to the Quality Workgroup and so of course we'll open it up for general Q&A, but I imagine that if today we feel that these…this work by Dixie and her team is good enough, we will have a very significant test case to apply it and Paul has asked for our responses by September 12th so we almost a month to run that exercise. So, questions?

Wes Rishel – Gartner, Incorporated

This is Wes.

John Halamka – Harvard Medical School

Yes, Wes, you had not e-mailed me, I was feeling lonely, please go ahead.

Wes Rishel – Gartner, Incorporated

So, let me say that I think that this work boils down, you know, what's great about the approach is what's not shown in the sense of the number of alternatives that were considered and yet left on the cutting room floor for simplification and that your comment that it has a huge value in terms of generating a discussion where all people start with a relatively similar grounding is a key observation. I wonder if the grid which of course is not committee work but came to the committee, I wonder if we can think of a situation where an imposed standard for healthcare ever was in the upper right corner that is meeting all the criteria for a national standard when it was made a national standard.

I'm thinking through a number of meaningful use stages…or 2011 addition and 2014 addition standards and I don't know that any of them would have met that criterion, I'm not saying that it wasn't a good decision to make them a standard and I'm not saying that it wouldn't have been valuable to have the kinds of discussions that this process enables during discussion I wouldn't have done anything differently, but I just would just like for us to recognize that we are…we seem to always be pushing the envelope if only because we're causing more precise attention on a narrower use case than has been the case before with a specific standard.

John Halamka – Harvard Medical School

And that's very well said, Wes, I mean, our challenge I think as technologists is we are constantly pushing the envelope because we want to move a functionality, a specificity forward and if we don't at times encourage the adoption of something that is emerging we will be stuck in the status quo. So, I think, and Dixie, look forward to your comments, but in effect you've established a classification system so that when we as a committee do make such an assignment like saying consolidated CDA is an emerging standard heading into pilot but think it's so important that it should be in fact included in regulations, we're doing that with full transparency and understanding of what we're doing to the country, assigning a standard that's in motion. So, Dixie, your comments?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, I think that that's exactly what we said that this should be used to inform and justify classification decisions. I think, as far as Wes's assertion, I think it's true for some areas of standards and not for others. I don't think that we're pushing the envelope very hard at all in the security area for example. I think most of the security standards that are in there do fall in that upper right-hand quadrant or it's not really quadrant…

Wes Rishel – Gartner, Incorporated

Yeah, 9th/10th whatever that is.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah.

Wes Rishel – Gartner, Incorporated

I feel that most of the issues I'm discussing come up when you're talking about standards that have functional content. Certainly we are more able to rely on standards that are developed for all IT when it comes to features of transportation and security and things like that than we are for content, you know, there's no…

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes.

Wes Rishel – Gartner, Incorporated

NIST doesn't evaluate standards for the relationship between the patient and an institution.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, I certainly agree that we're pushing…we're certainly advancing standards in the health domain, absolutely, yes.

Jim Walker – Geisinger Health System – Chief Information Officer

John?

John Halamka – Harvard Medical School

Yes, I know I have Jim Walker in the queue and Leslie Kelly Hall. So, go ahead Jim.

Jim Walker – Geisinger Health System – Chief Information Officer

I just want to support what Wes said and also I think make the logical sort of next step, which is basically, Dixie's team has created a really neat prediction rule and the next step would be to say, okay when we make decisions based on this assessment we need to have a discipline of coming back in six months or year or whatever and saying, okay how well did we predict how this was going to do, what's the correlation between our assessment and how it actually worked on the ground, so that I think we could refine the prediction rule, get better and better at anticipate, you know, at correlating the assessment with what's likely to happen on the ground when we implement it and we could get smarter about this as we go forward partly because of this tool.

John Halamka – Harvard Medical School

I completely agree, so when we think of continuity of care document it was an emerging standard that was included in Stage 1 and I think as it went into pilot and then into full production and became a national standard we learned so much about its limitations that we then revised it and came up with consolidated CDA as a replacement. If we are going to introduce something emergent we better have the responsibility of evaluating its success or failure and revising it or dropping it as necessary. Well, Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Senior Vice President for Policy

Thanks, John, so I also commend this work and I think that there is an opportunity to evaluate new use cases of existing standards and I wondered how we could use this tool to help with that, you know, the consolidated CDAs example, using that in a variety of different ways, do we need to accommodate that in our evaluation tools, so that's a question, new use cases of existing standards or do we assume that as long as that standard is up in that upper right-hand quadrant or emerging and we agree to it that it doesn't matter what the use case is, so, that's a question.

And then also, one of the things we discussed is this notion of when can standards actually inform policy and even though it's not yet in a pilot phase the existence of that standard could help create new opportunities and policy. So, in the Meaningful Use Workgroup we are often listing out here's a function we'd like or here's a direction we'd like to go, is there a standard, yes or no, if there is one than often times the policy says "okay, well there is a possibility to act on that, let's go for that." Where there isn't a standard as well not so much "I don't think we should consider that." So, I wonder how do we balance this idea of standards measurement against also standards as informing innovation and new policy.

John Halamka – Harvard Medical School

I think, again, very good point. Let's use as a case example the Meaningful Use Workgroup is currently working on care plans and asking what should be included in transitions of care for care plans. Well, I think, Dixie, if we use your criteria and you look at the current S&I framework activity on longitudinal care coordination, which you can say is, it is emerging and it is going to be heading to ballot, but there is a trajectory that I think we could all see of how it goes from emerging to pilot to national that may provide enough directionality to the HIT Policy Committee and its Workgroups to say, you know, by 2015 it will be on that black arrow that Dixie has drawn and in effect give them the comfort to make a policy decision that is going to be aspirational today, but Dixie your comments?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, I agree and I think that standards should, the second part of your question, standards should help inform policy and I think that HITECH recognized that when they created the Policy and Standards Committees and that the increasing collaboration between the two committees also attests to a recognition of that need that it really is…both standards do have to be considered when developing policy.

John Halamka – Harvard Medical School

Well, I also have Walter Suarez in the queue.

Walter Suarez – Kaiser Permanente

Yes, thank you, John, terrific work, Dixie, as everybody has said. And the point I guess and suggestion I wanted to make is I think this is such good work it needs to be put into place right away. My suggestion was going to be threefold. First of all, I think this should be communicated to all the SDOs basically and to the organizations that are developing standards, as a reference point, not as a kind of we must meet this kind of a thing but really as a reference point for them to know that, oh, look at what we are going to be, you know, evaluated against for purposes of being adopted as a standard and I think it's very valuable for them to have this information. I know it is available on the web and everybody can use it, but I think a more formal communication to SDOs would be helpful.

The second one is communicate this immediately also to the S&I framework Initiatives which are looking at precisely these kinds of issues, you know, what are the standards that can be adopted for specific use cases within specific initiatives and so having this type of criteria, in fact some of them have developed their own criteria to start the work back before this criteria existed or was in place. So, I think communicating that immediately into the S&I framework so that they can begin to incorporate this into their work I think will be very valuable.

And then, lastly, I think this certainly, maybe this is stating the obvious, but this is certainly the guiding process and the guiding criteria for us, as the Standards Committee, to really follow through in any future assessments of standards and maybe that's what Paul was asking you John about with respect to criteria for standards for quality but then for standards for anything, really for any other standards that we would be looking into for, I guess at this point would be Meaningful Use Stage 3 and any future efforts. So, those are my three suggestions and some very immediate steps that I think will truly benefit the work that is being done in different areas and different projects.

John Halamka – Harvard Medical School

So, of interest, Paul Tang is really asking Dixie's tool to be used as a predictive decision tool.

Walter Suarez – Kaiser Permanente

Yes.

John Halamka – Harvard Medical School

You know, that is knowing what we know today and knowing what's in process do we feel that in 2015 there will be standards of reasonable maturity that will support their aspirational workflows. Dixie, comments?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Well, I think Walter has a really, as usual, really, really good point, it does need to be…need to get out there and maybe we could even consider publishing it somewhere.

Walter Suarez – Kaiser Permanente

Exactly, I think that would be great.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes.

John Halamka – Harvard Medical School

And, so getting this to the SDOs who they understand that when we're evaluating their standards we're using a set of objective measures and we take some of emotion out of it, because so often people say "well, wait a minute, well we used that as a connect-a-thon standard it's highly mature." Well, here are the objective criteria we're using for implementation, adoption and all the rest. So, I think that would be very helpful. Well, Doug Fridsma has joined the call. Thanks, very much Doug. I believe Wes Rishel is also in the queue and Wes, thanks for sending me your ham call radio sign, so should I refer to you as AF6YH in the future discussions?

Wes Rishel – Gartner, Incorporated

That's Alpha, Foxtrot, Six, Yankee, Hotel, thank you.

John Halamka – Harvard Medical School

Okay, please go ahead.

Wes Rishel – Gartner, Incorporated

That's what happens when you send only a signature line. I wanted to particularly stress that this is really a bidirectional relationship between Policy and Standards that it is easy to get ahead of…given what we have observed, which is the time it takes industry to react to a new standard and have it deployed to a level with a level of consistency that it can honestly be a meaningful use criterion, it would be easy for Policy to get ahead of what's practical in Standards. I think Policy people have a good idea of what's going on in many places and tend to look in those areas and that's helpful but this feedback loop is particularly important. Likewise, we on the Standards Committee have to recognize that the seriousness that is given to our work is in large part driven by the recognition of the Policy Committee in terms of potential of meaningful use criteria.

So, we have this economic lever which can't move the world, maybe the fulcrum is there but the lever is not that strong, but when we come to a reasonable coherent agreement between Policy and Standards we've got a very strong opportunity to move the world.

John Halamka – Harvard Medical School

Great, now a process question for you, Mary Jo, we've heard comments from the committee and we have a presentation from Dixie that gives us a set of criteria we can now adopt in practice and in fact, as I said assignments to use it will be forthcoming shortly, do we need the committee's formal vote to accept these criteria and apply them or what process might you recommend?

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Well, I'd certainly like to consult with others and I'll have MacKenzie chime in too. My assumption is that these would certainly have the greatest strength if you turn these into a transmittal letter to the National Coordinator then they do become a formal recommendation. Other methods of distributing them and getting them out there to the field, I think should…are really welcome and ONC can certainly use some channels, we can take a look at the various ways that we could reach out to people, but I think all of you on the committee have perhaps the most direct connections. So, I don't know, Mackenzie, do you have anything to add to that?

MacKenzie Robertson – Office of the National Coordinator

No, I would just agree with what Mary Jo just said. I think for them to come as Policy Committee recommendations it would be important to actually transmit them as such.

John Halamka – Harvard Medical School

Standards Committee recommendations.

MacKenzie Robertson – Office of the National Coordinator

Standards, sorry, yes, Standards Committee.

John Halamka – Harvard Medical School

And so, well let me then just ask are there are any other revisions, items of discussion, people have been e-mailing me their cards for Q, I just want to make sure that before we would go forward and say "yes" we will create a transmission letter incorporating Dixie's Team's recommendations that we've had full discussion of the topic.

Jonathan Perlin – Hospital Corporation of America

Okay, John, why don't we take this then as a consensus for sending it forward as a recommendation, unless I've heard incorrectly, and I think Jim Walker's framing that, you know, really this is a predictive model, a decision support predictive model that can be tested and part of it is, is that we also commit to revisiting the work to see how well it serves as a predictive tool.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

You know, Jon, we can…I was thinking that I might just steal Jon or Jim's recommendation as one of our recommendations…I think that that's really a good recommendation to just add to our transmittal letter, you know, in that…on the slide that has our final recommendations that we say plain…that we…you know, we already say that national standards should be revisited periodically but that to that we add this, add a process to validate the classification and go back and validate and refine the use of this tool as a predictive rule. I think that's good and we could capture that in the transmittal letter.

John Halamka – Harvard Medical School

And, in fact, Mary Jo has e-mailed me an important question which I just raised with the group, which is if Paul Tang and the Meaningful Use Workgroup is seeking our input using this tool to evaluate some of the maturity of some of the standards that they may need by 12th of September that is in fact before our next Standards Committee meeting and, again, matter of policy, Mary Jo, I believe generally what happens is Workgroups are assigned tasks, report back to the full committee, the full committee then reports to ONC which transmits to the Policy Committee, but I think in this case, because of time maybe what we can do is assign our Workgroups a review of some of the Policy Committee or Meaningful Use Workgroup questions recognizing that their answers using this tool will be of a preliminary nature, we provide that as guidance to the Meaningful Use Workgroup and to discuss it in detail at our next Standards Committee meeting? Would something like that work procedurally?

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Who are you asking?

John Halamka – Harvard Medical School

That was Mary Jo; it was a Mary Jo question.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Right, it was Mary Jo's question, Mary Jo's suggestion, so, again, MacKenzie, it seems to me that this would work because we did have clearance from our general counsel that Workgroups can talk directly to each other without going formally up and down chains. So, certainly that first step of the Workgroups giving direct feedback to the Policy Committee work, to the Meaningful Use Workgroup I would categorize it that way, that they're not giving guidance directly back to the Policy Committee they're giving it back to the Workgroup and then you could follow-up in your September meeting and take a look at what has been sent and then if you want to make any revisions based on that a revised transmittal from the Standards Committee back to the Policy Committee.

John Halamka – Harvard Medical School

Okay, it seems like we have a process. Well, certainly, Dixie, I want to thank you for this extraordinary work and once again you have set the standard, you've set the bar for creating such high-quality that the Standards Committee just says "looks good." And so, Jon Perlin, let me turn it back to you. I believe Farzad is joining us for some remarks.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

And, I just wanted to thank the committee for their excellent interest and inputs into this work.

Jonathan Perlin – Hospital Corporation of America

Again, on behalf of everybody, Dixie, many thanks to you and…someone is getting some feedback there. Many thanks to you and team members for just a terrific contribution, I think today it really marked something that not only helps this effort but coordinates so well with our colleagues in the Policy Committee and appreciate the timeliness of this. Let's see if Dr. Mostashari has joined. Farzad are you there?

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

I am.

Jonathan Perlin – Hospital Corporation of America

Good morning.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Good morning, thanks everybody. I just want to make a brief observation that I think is in line with a lot of the discussions that we've been having already, which is that the conversation is moving, gratifyingly so I think, from the standards per see to more the real-life, real-world implementation and the wonderful problems, I'll put it that way, because we should be so lucky to have such problems that come from actual implementation and the commitment to the ideal that we are approaching, we hope to approach asymptotically of "it just works" interoperability and exchange, and some of the important strategic approaches to that such as Wes has raised around bilateral asynchronous upgrades and so forth.

But a renewed emphasis I think will be needed for us to move again from where we have been which is accelerating consensus around standards that meet the criteria of not just maturity but also usability, adoptability and so forth to their actual real-world implementations, implementation guides, tools, resources even communities that will take those standards and actually put them into practice.

And an emphasis on testing that moves beyond compliance to schematrons to actual functional tests of interoperability and exchange and the need to keep that communication loop tight between those implementers in the field, blessed are they, and the standards development and implementation guide, the standards development organizations and bodies like this that would then take that real-world experience and see is there is a need for modifications, evolution, development to those standards to the implementation guidance, to the testing tools and to really keep this engine moving along.

I believe that that's the stage that we are at where we do have now on an important and substantial set of contents messaging and transport standards we do have substantial consensus and we will be moving forward with implementation approaches to those, but as we do that we will learn as the implementers in the field begin to use those there will be questions, there will be gaps, there will be optionalities that need to be closed and they will need to try things, and yet we will need to be brutally honest with ourselves about what is working and what is not working so we can learn and kind of with a lean start up ideology of taking quick iterations and knowing if it's working or not working, and closing the time between iterations that have to be sub-regulatory. We can't iterate on that level within larger regulatory frameworks which I think we've clearly heard and understood.

So, I think that, I believe that we are well on our way and what I would ask us to consider is how do we bring in closer the implementations in the field whether it's through the states as one vehicle, whether it's through communities, whether it's through vendors, how do we bring in those field implementations and experiences ever closer and make sure that we learn as quickly as possible and I will leave you there.

Jonathan Perlin – Hospital Corporation of America

Well, as always, Farzad, thank you so much for terrific words. I think that's just absolutely fabulous as a segue between where we have been in terms of not only the longer history of our work but the supporting conversation and where we're going in terms of the next topic, the Implementation Workgroup. Indeed this morning when we initiated the call we've already talked about the fact that our conversations and the environment around us have changed from really the speculative nature of what might be to what can we do with information that's beginning to emerge and that is producing the vehicle for incredible feedback. Would you like to have any conversation at this point, Farzad?

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

No, I think it will be a good transition to the Implementation Workgroup.

Jonathan Perlin – Hospital Corporation of America

Terrific, well with that, let me thank you, as always, for your work and just really the continuing heroic efforts of ONC. And we'll turn to Liz Johnson and we really so appreciate you're doing exactly what Farzad is asking which is to be sure that we are getting as robust input as possible to sort of rectify processes so that this virtuous cycle can really accelerate even faster.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Thank you, Jon, and thank you, Farzad, I think what you've just both said is absolutely the work of the Implementation Workgroup as we are talking with both providers and our vendors, you know, we've began to recognize some of those challenges and I think today we come back to the Standards Committee and to our Chairs to say we have a transmittal letter we're putting in front of the group today for your input that speaks specifically to a concern we have related to the publishing of the Meaningful Use Stage 2 guidelines and how critical it is that we be able to take those guidelines and do the things we're talking about which is really, you know, putting forward motion the use of health informatics to improve patient care.

So, with that, we sent out yesterday, and I would encourage all of the Standards members to pull up the actual letter because I think it will be much easier for you to follow the conversation with that letter in front of you. I presume, MacKenzie, that we are going to project it, but again, it may be easier for you to go to your attachments on your invite and actually open up the letter itself. So, MacKenzie, are we going to project the letter?

MacKenzie Robertson – Office of the National Coordinator

Alison or someone at Altarum could you please…?

Rebecca Armendariz – Altarum Institute

I'm pulling it up now, yes.

MacKenzie Robertson – Office of the National Coordinator

Great.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Great, thank you. So, we are putting in front of you a letter that we would like for you to consider for transmittal that really does speak to the timeline and the process so that we'll be prepared with both certification criteria and the test procedures on time. This will relate to both Stage 2 of Meaningful Use as well as addition 2014 certification requirements.

So, in the past we have requested that we have 18 months between the time that an NPR is published and we have final regulations, and you know, we are now sitting on that deadline, and so we've come back to say, based on the fact that we'd like to reiterate that recommendation and that we allow for time for software development and implementation, we'd like for you to take several considerations under your advisement and you would provide to us any feedback that you have for modification of the transmittal letter, and then we would turn to our Chairs to ask for that transmittal letter to take place.

So, if you'd go to the second page of the letter, please? We really have outlined for the Standards Group sort of the objectives and the motivation behind this request. We know that it takes time to develop the technology that supports meaningful use. We know that we need quality assurance so that when that technology is rolled out its adequate and ready for field use.

We are working clearly with today the Implementation Group is working with the certification and testing procedures and in fact in future meetings you will see us present to you clinical scenarios based on the testing that is going to be needed for Meaningful Use Stage 2. So, we are clearly working down that path, but we know there's a time element that's really critical and that we need the labs that are going to be doing our testing and certification for Stage 2 to be ready, that once that has taken place and we have the upgrades and testing ready we need to implement and then we need to train our physicians and clinical staff with the upgraded technology.

We need to be able to implement the interoperability connectivity so we can get to meaningful use.

And then, obviously just actually getting it out in the field and, you know, having it being used so that we can measure the results of the use, so, many steps. We've tried to articulate those in as simplistic way as possible, most of us on the committee work in the field and understand that from the time that you get the regulation that needs to then be built into code, that needs to be tested, certified, implemented, trained and then measured is a very intense process even in the best of times.

So, given that, what we're going to ask for is fairly straightforward. We know that the NPRMs were published in mid-March and that we are now approaching, in fact are at the midpoint for the 18-month window. So, if you go to the second to last paragraph of the second page of the letter you'll see that we recommend that we expedite the publication of the rules and I think that's a given. We have seen extraordinary work coming out of ONC and other bodies to get these regulations ready and we know we are very close to the publication, but we know that that publication has not taken place.

So, we're going to start at the bottom of page 2 and we're going to talk to you specifically about our recommendations. So, I'm going to pause for moment to make sure you are there; it's in a bulleted format. There are three recommendations that are bulleted out and two additional that are in paragraphs. So, the first one is that for our eligible hospitals, our critical access and our eligible providers where 2014 will be their first reporting year we don't need any additional flexibility, they will be given a 90 day window to achieve those standards in 2014. So, we believe that can stand as currently written.

The second recommendation, which is the second bullet, which starts on page 3, would be that for the eligible hospitals, critical access and eligible providers that require a full year window for Stage 1 in 2014, those whose first year for Stage 1 year was 2013, we recommend that they be given an option of either using addition 2011 or 2014 for the beginning of the reporting period.

And the third recommendation and then we'll go back and talk with each one of those recommendations with the committee, the third recommendation is for the same group of those who will be certifying that would currently start Stage 2 in 2014, which would be October 1, 2013, and you either start at Stage 1 in 2011 or 2012, so that would cover the entire group, we recommend allowing using either 2011 or 2014 certification and Meaningful Use 1 Stage measures at the beginning of the reporting period. So, those are sort of what standards would apply to each of the groups.

Now, I want to talk about two additional recommendations that we have. We recognize that for Stage 1 for use, Stage 1, so they are in their second year, there may be an interdependency between Stage 1 criteria and the addition 2014 that's been recommended under the NPRM, in these cases we recommend either allowing attestation under Stage 1 for the full year or recommend that we allow attestation under the updated criteria for a 90 day reporting period. And, I know I'm throwing a lot at you. Hopefully, most of you read this last night.

And then for the final group, which is our final recommendation, we want to insure that the widest set of eligible hospitals, critical access hospitals and eligible providers achieve Meaningful Use Stage 2 in 2014. So, based on the fact that we want to see that sort of adoption we would recommend the use of a 90 day attainment period for Stage 2 measures during 2014.

We recognize clearly that this is going to create some complexity in attestation, because of the dual potential, but we really do believe that it's going to be critical to allow that additional time that would follow October 1, 2014 based on the final regulations being published to be prepared in terms of the technology, in terms of testing certification and in terms of the actual implementation of the products and then finally, of course our measurement of the results of that implementation. So, Jon and John, I would recommend that we then go back to the first recommendation and walk through them one by one so that we can get organized input from the Standards Group for each one of the five recommendations.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

This is Farzad; I guess I'm a little confused on process.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Okay.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Liz, I thank you and the group for this thought, a lot of what these recommendations…so two things, one the recommendations I think the letter seems to have the OMB Director addressed and the committees make recommendations to the National Coordinator by statute not to OMB Directors or other people.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Okay, all right.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

And, I mean it shows understanding of the process here, but I think it's a little bit out of step in terms of what this committee's role is.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

All right.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

And clearly, we received recommendations from the Health IT Policy Committee regarding timing of meaningful use that incorporated many of these issues. We also have clearly, in the time when we were open to receiving comments and recommendations including from the Standards Committee on the rule, that is the window within which we can, by law, accept comments for input into the process. So, I appreciate the sentiment and the clarity is clearly something that has been discussed before. I'm not sure whether a Health IT Standards Committee recommendation at this point is, from a process point-of-view, is appropriate, if you see what I'm…

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Of course I do and I think, you know, Farzad, very good points and again, some of our advisors we should have potentially just sent it to the National Coordinator and so for that, that's a very easy fix. I think the concern that was expressed and we brought forward to the committee for exactly this kind of discussion was, although we had submitted these recommendations in the past even prior to the NPRM being published, it wasn't reflected in the NPRM. So the Implementation Workgroup brought forward, again to the Standards Committee, a reiterated recommendation.

If the timing is wrong then we certainly accept that and for the record, you know, we'd certainly want that it was reintroduced, but we clearly respect the process and the appropriate timing of whatever, you know, both the Standards Committee and you as our leader from the ONC perspective would make recommendations back to us.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Yeah. I think as far as messaging and raising the concern, it certainly has been raised before and I don't think it is inappropriate to raise it again, I don't know that a Standards Committee vote on a formal recommendation would be appropriate at this time.

The other thing that I really would love to have the group focus on is, given whatever the timelines end up being, what can we do to make it the best of circumstances as you put it, what can we do to help accelerate and improve not only the compliance with the letter of the law around certification but actually making meaningful interoperability and exchange part of Stage 2 and that is really where, aside from the policy issues of the timing, what I really would love the Implementation Workgroups help on is working with industry and others to shorten that timeframe and to find creative ways of getting a running start on the standards development implementation testing and certification, and so forth.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

And, I think, you know, we take that charge very seriously and in fact…and I feel confident that you're aware that we've already been through all the certification criteria with the group and we are now working on the testing scenarios, and as committed as soon as we have final regs to then quickly provide our immediate input back into both the testing criteria as well as the scripts themselves so that we can immediately then help escalate the use of those scripts into our certification bodies and then it would move on through the process as you suggested, because like yourselves we will put our concern forward but we will also work diligently to make Meaningful Use Stage 2 successful, because at the end of the day everyone on this committee and everyone on the Implementation Workgroup is committed to what this is all about, which is again, meaningful care for our patients. So, we are absolutely on the same page.

Jon and John, given Farzad concerns and the Standards Committee what would you suggest in terms of our moving forward?

John Halamka – Harvard Medical School

Well, just one comment is Farzad the genesis of this letter came out of the fact that many members of the Standards Committee wanted to be extraordinarily supportive of ONC and recognizes the regulatory complexity of moving anything from an NPRM to a final rule and I think the gist was if we as a body said, it is really important to move this quickly and so, you know, folks at OMB, you know, if you're sitting on it, you just need to know time is a wasting and we're not going to be able to, as a country, adhere to deadlines if it is delayed much longer.

So, I guess, I would ask, Farzad, you know, is there any transmission, any indication that from the Standards Committee that would be helpful to ONC, as Liz has said, obviously we will be focused on accelerators given whatever timeline is dealt but it there anything else we can do?

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

Yes, I appreciate the sentiment and I guess what I would say is that there is a broad and deep commitment throughout all parts of the administration to get this moving and we will be…soon we will see the results of that broad and deep commitment. Thank you.

John Halamka – Harvard Medical School

Jon Perlin, I mean, any other comments? I mean, I guess the…in fact the airing of this issue at today's meeting with some detailed recommendations in effect brings to light our concerns, but I think what we're hearing from Farzad is that a formal letter that goes out to CMS, OMB, etcetera, may not provide additional acceleration at this time and therefore at this point the discussion and the sentiment was the most important thing we could do.

Jonathan Perlin – Hospital Corporation of America

I think that's absolutely right. I think there's a great deal of passion around wanting to be able to move forward swiftly with Stage 2 and, you know, just let me step out of the sort of neutrality of the Chair and just note as a provider or speaking with vendors, all are really committed to next steps but concerned about constraints of implementation and timeline. And, I want to thank Liz and the Implementation Workgroup for really putting that on paper in a more formal way.

I think it is part of the record of the committee and I hope in, you know, the sense, John Halamka, of what you just described really to support for ONC from the Standards Committee in the context of concerns about timelines that perhaps it's very presence to date in its form, as its presented right now maybe helpful in just reminding some of the folks who are less proximate to this discussion that anything they can do to accelerate would really help achieve really the objectives of meaningful use more timely. So, unless, Mary Jo, you have a different process recommendation that I believe would be an approach that would support the guidance we received from Dr. Mostashari.

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

I think that's appropriate.

John Halamka – Harvard Medical School

Now, Jon P., I believe Arien Malec wanted to respond.

Arien Malec – RelayHealth Clinical Solutions

Okay, thanks, yes, so I accept and understand the process issues at play, the one piece of this that…and I also understand what Farzad just said in terms of hoping that the timeliness considerations are met rapidly, I guess that might be a little redundancy but that's okay, the one piece of the letter that I want to make sure does get a full airing is the notion that expediting work sometimes in the government context, particularly given all of the regulatory process, despite everybody's best intentions can sometime take time and want, and I know that Farzad does understand, but want everybody to understand that if there are additional things that time, additional reconciliation, etcetera, process issues that come up the longer it takes before we have the full, particularly the testing scripts in front of us, the more risk we're bearing on the process and so just that understanding of the relationship between the timeliness of the testing scripts and the risk, the downstream risk that we're creating is something that I want to make sure is fully understood.

And then also understand that this risk is not linear, that because we're compressing cycles and compressing work to a fixed deadline you get to a point where a week delay is not, you know, a linear addition of risk, it may be a nonlinear addition of risk and so for some hospitals you may have passed over the critical window that is literally, you know, make or break from a clinical quality perspective and a patient safety perspective with the hospitals that are faced with the choice between accelerating technology and option to meet their financial plan, and also accepting the safety, and process issues that come with physician training, and technology adoption, again, just recognize that there is a nonlinear relationship between timing and risk.

Wes Rishel – Gartner, Incorporated

John?

Jonathan Perlin – Hospital Corporation of America

Yes, is that Wes?

Wes Rishel – Gartner, Incorporated

Yes.

Jonathan Perlin – Hospital Corporation of America

Go ahead.

Wes Rishel – Gartner, Incorporated

I recognize that there are some really fundamental issues working here, one of which is that there are deadlines fixed by legislation that don't allow for any adjustments associated with process issues in issuing regulations, that's, you know, ONC is not unique in having to deal with that situation, I think it's probably more common than not. I think that there is some overlap in planning cycles where we may have missed the window to adjust for the implementation times that are required of industry for Stage 2. I'd like to see us therefore have a two pronged approach given the gravity of this issue. The first prong is as we all agree, Farzad has requested, and we all agree work to provide whatever systems we can in accelerating the processes to provide the maximum benefit and the minimum harm within whatever the final regulation says.

The second is review those aspects of the regulatory framework that might be examined with regards to Stage 3 such that perhaps deadlines are keyed to the issue of the final regulation or that entire calendar year requirements for qualification are looked at more closely versus shorter qualification times so that there is more flexibility in the industry to deal with the inevitable process delays during the regulatory development.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

So, I think Jon and John, you know, I think…and Wes summed it up well, I think we all as a Standards Committee recognize that the concerns that were expressed by the Implementation Group are those that are universally held. I also think though that we clearly understand the forward path of given the NPRM should be out very shortly we need to accelerate everything we can do to help both the vendor and provider community in achieving the requirements.

The secondary piece of that, which is exactly what I've written down here, is that the Standards Implementation Workgroup will be committed to, you know, following and preparing for Stage 3 in an even more assertive way of saying, you know, do we have the right steps early on to influence our ability to prepare for that. So, I think the work is well done and I think we can move forward noting in the minutes the work of the Implementation Group and not request a transmittal letter at this time.

John Halamka – Harvard Medical School

That sounds good to me.

Walter Suarez – Kaiser Permanente

John, can I…this is Walter, can I jump in?

Jonathan Perlin – Hospital Corporation of America

Please do.

Walter Suarez – Kaiser Permanente

Yeah, I mean, certainly this is a very critical topic and clearly the message about the importance of publishing the rules as soon as possible is heard, but I think there are two additional outcomes that I think would be helpful to consider. The first one is I think there is going to be a need to monitor more carefully over the next 18 months the ability for the industry and the progress that the industry will be making in achieving these 7 or 8 points and perhaps more that are listed in the second page of the letter.

And my suggestion there was going to be that the Implementation Workgroup consider holding perhaps a hearing around, I don't what, quarter one or quarter two of next year to assess the progress towards achieving, you know, preparation and planning, and successful transition towards meeting the 2014 edition requirements, because I think that is one way that we can become aware of and be alerted of any industry issues that organizations will face as they get closer to meeting these new requirements, October 1st of next year. So, monitoring is one important one and perhaps, again, holding hearings to understand where things are will be valuable.

The other one is, I think, you know, creating a template of a timeframe for what would be the worst-case scenario, if you will, or the, you know, the worst situation in which the process comes out to be that these 7 or 8 steps, again listed on page 2, would need to be met at certain points over the next 18 months. I think it will be helpful to have such a template timeframe published and made available so people know that if I don't have my EHR software in place by X date I'm really going to be not able to achieve and meet the requirements, that type of a template guideline has been helpful in other areas and I'm referring to the administrative transaction standards that we've been, you know, required to meet over the last 10 years or so, where, you know, industry organizations have been able to publish and make available, you know, templated timeframes for meeting certain milestones during the transition.

And so, I suggest that perhaps that's another work that either ONC or with the help of the Implementation Workgroup can we develop this template of what is the timeframe by which…if you don't have these steps met during…these milestone steps met during the transition period between now and October of next year, you know, you'll be certainly in trouble.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Well, thank you, Walter for that suggestion. We'll take…we have another meeting on the 23rd and we'll have that discussion, thank you for the suggestion.

Jim Walker – Geisinger Health System – Chief Information Officer

Liz?

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Yes?

Jim Walker – Geisinger Health System – Chief Information Officer

Jim Walker, just real briefly, maybe it's implied in what Walter said so well there, you know, I'm not sure we've had in mind as one of our audiences the boards of directors and the CEOs of healthcare delivery organizations and I think that is one thing we could do very practically so that a CEO or a board could have this kind of timeline and say, you know, nothings hard and fast, but, you know, if you expect to, you know, to get this delivered this is a timeline that you could use with your project team to measure your organizations progress.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

That's an excellent suggestion. I think it also, as we've often said in the Standards Committee, as well as the Implementation Workgroup, you know, setting some realistic timelines so that the industry better understands particularly those who lead our organizations but are not intimately involved in, you know, taking these implementations and making them reality inside and outside of the our organizations. So, another good suggestion.

Jonathan Perlin – Hospital Corporation of America

Well, I appreciate those comments. I think they are very much in line with what Farzad was asking for, what sorts of things, what is the feedback that the industry is providing and I think the general sense of one vehicle to get more information and two outside of process of the letter looking at an optimized timeline that is appropriately expeditious but allows the cadence of the development cycle and implementation testing on the vendors end and then, you know, the roll out and testing needs to occur in a provider environment.

Every time we are making upgrades to support next stages of meaningful use, I'm stunned by how long it takes to test for example pharmacy dictionaries which may have 10s of thousands, if not 100s of thousands across multiple facilities discrete line items that need to be validated so that there is fidelity of information. I think those are very important points that the committee has offered.

Well, let us then sort of consolidate around this that we've had robust discussion on the record of our discussions today are a set of sentiments that we hope will be useful to the Office of the National Coordinator and their conversations with other HHS and federal agencies in terms of that process. The discrete recommendations for more formally contemplating a timeline as well as…and we'll coordinate with Mary Jo whether it's the appropriate vehicle or otherwise, or coordinate with MacKenzie whether it be hearings or the vehicles to get the robust input that Dr. Mostashari really commended to us as the best way in which we can support the process. John Halamka, anything else on your end before we move to next topics?

John Halamka – Harvard Medical School

I just want to thank everybody who put together such a thoughtful proposal and I think, you know, we will hope that we will get both the final rule on the testing and certification criteria in a very timely manner, and if for some reason there should be a delay, Liz, I am certain that your work will be highlighted as possible alternatives in addition to the acceleration efforts that we will all put forward.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Thank you, John.

Jonathan Perlin – Hospital Corporation of America

Liz, there anything else that you'd like to bring forward?

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

No, Sir, I think what we're going to do is at the next meeting, we're going to bring forward the clinical testing scenarios and so we can look forward to that.

Jonathan Perlin – Hospital Corporation of America

Terrific, we will appreciate that input and let me join John Halamka and the members of the Workgroup and others for really a very thoughtful, provocative and timely conversation.

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator

Jon, this is Judy Murphy, I would just like to commend the Implementation Workgroup for their work on the testing scenario scripts, this has just been wonderful work, I've been following it behind the scenes with Carol Bean and I'm really excited about that as we go forward with Stage 2, so, thank you team.

Jonathan Perlin – Hospital Corporation of America

Terrific, thank you so much for those kind words, I know it's appreciated because, as we all observed the time of the e-mails indicates that the midnight oil and the weekend oil is burned fairly frequently. With that, let us then go to the Clinical Quality Workgroup and welcome Jim Walker.

Jim Walker – Geisinger Health System – Chief Information Officer

Thank you, Jon. Just as an introduction the Quality Workgroup doesn't have any decisions that we're looking to the Standards Committee for today, but obviously welcome your input. This is primarily an update on our, primarily ONC and NLMs accomplishments in standing up value set repository. There are slides do we…okay. So the next slide then is just to remind you, these are the recommendations that the Standards Committee approved that create the background for the update I'm going to give you.

So, the first was that we establish NLM as the single validation authority for value sets for MU 2. The second was that we expedite, that ONC expedites recommendations of the Implementation Workgroup on the dates you see and then the vocabulary taskforce, just about a year earlier, for a public value set repository. The third recommendation was that we base this work on the IHE shared value sets profile and a related common terminology service for managing the vocabularies so that we have a standard management system. And then the fourth recommendation was that there be a web service that would provide both human readable and machine readable MU 2 value sets, the first for organizations who need to work that way and the second for greater efficiency.

So, then the next slide is just a graphic of that to remind us that there is a phase 2, which we intend to pursue after MU 2 is put to bed, but today's discussion is about that right hand side of the repository concept. Curation is sort of step 1B or something, so it isn't really in view in today's recommendations or today's update, but is more a future as you'll see.

So, then the next slide has the accomplishments which are really remarkable and gratifying. ONC and NLM have worked together in just remarkable fashion to I think really move us forward to where we will have a public utility that is critical for supporting MU 2. So, the value set authority has been established by NLM. The second point there, the value sets have been validated and that validation process is identified needs that have been referred back to the value set authors who are making the appropriate edits and NLM, and ONC together are tracking those issues to completion, and we're early in that process, but it's going well.

The second, the third bullet, sorry, is that the shared value sets and the CTS-2…the shared value sets are being used and we're looking at, they're looking at CTS-2 as an additional standard for making future use more usable. And then the fourth bullet, all of the agencies named there are collaborating on delivery mechanisms for the value sets, so, the web-based delivery.

The next slide, so then the next steps beyond MU 2 include formalizing the governance for the value set authority. One of the things that we did to get this up rapidly was to defer the question about formal governance until we got the public utility up and available, and then you can see the other sort of services that will be…need to be worked out and provided post MU 2. So, I welcome comments, I think ONC and NLM, and the Quality Workgroup all would appreciate any comments that help us get this done more usefully and quicker.

Jonathan Perlin – Hospital Corporation of America

I will go ahead and open for comments. John Halamka anything you'd like to offer to start with?

John Halamka – Harvard Medical School

Let me just…recognizing that NLM is doing some extraordinary work. Jamie Ferguson led a call regarding FDA universal device nomenclature, so Jim Walker, as you sort of think of value sets and vocabularies this is a very extensive body of work ranging from the simple to the highly complex and so with many moving parts. I know that funding has been obtained by NLM and NLM is diligently working on it, and once this infrastructure is built then, as you'll see from the questions circulated by the Meaningful Use Workgroup, interesting ways of utilizing it like creating ad hoc distributed queries that would go out to EHRs to create virtual registries so that future versions of meaningful use wouldn't necessarily require hardcoded quality measures or hardcoded registries but in fact would support sequel-like queries based on this nationally curated set of vocabularies that would result in numerators and denominators of an ad hoc variety.

So, this work is foundational to all the future of Meaningful Use Stage 3 aspirational goals for quality reporting. So, certainly, you know, as Betsy gets into the details of implementing this I think everyone on the Standards Committee stands ready to help bring this to reality as quickly as possible.

Christopher Chute – Mayo Clinic College of Medicine

This is Chris Chute, I certainly agree it is foundational and I also agree that we're all ready and willing to roll up our sleeves since it is a critical path of dependency. I would comment that as far as the implementation is concerned and the goals for value set discovery and reuse the CTS-2 community, the Common Terminology Services 2 community has been working with NLM to explore whether a simultaneous use of SVS and CTS rather than deferring CTS could be explored.

The reason this is important is actually SVS is not a standard, that's a misnomer, whereas CTS-2 has been opted by OMG and several others and furthermore has the robust capacity to handle not just value sets but full RESTful services and terminologies and terminology value set integration as well as authoring, that's all incorporated into CTS-2, so I simply wanted to update the community that, this is a direction that is being, at least explored although what Jim reported I guess is officially true, we are, we here being the CTS-2 community, are hoping to have a simultaneous release.

Jim Walker – Geisinger Health System – Chief Information Officer

Thanks, Chris.

Jonathan Perlin – Hospital Corporation of America

Other thoughts, anybody?

Wes Rishel – Gartner, Incorporated

This is Wes.

Jonathan Perlin – Hospital Corporation of America

Please, go ahead.

Wes Rishel – Gartner, Incorporated

Two comments, one I thought but Jonathan's introduction was superb, I mean we tend to get all excited about the engineering genius about building the pyramids but this is moving the blocks of stone and a huge amount of work.

Second, I would like us to maintain a clear division of labor, if you will, between distributing, updating, creating the value sets and implying standards of how they are implemented inside an electronic health record. So, without a good knowledge of CTS-2 I am concerned that it may be more focused on the operations against the value set during the execution of code in an electronic health record then about what is essentially a huge configuration management process for a site, which involves bringing in new or updated value sets, analyzing them against various dependencies they have in value sets such as templates and clinical decision support rules, and in the situation where the value sets are equally important to the revenue cycle management system as to the electronic health record system and to dozens of other clinical systems create controlled internal releases to these internal systems that may have ad hoc methods of implementing codes inside them. Thank you.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David and I would like to second Wes's notion just from the vendor perspective I think it's admirable to look for flexible sets of web services and download capability for the value sets but it's unlikely that a vendor would build a runtime dependency on a value set query into a product like this and I think it's also quite likely that many value sets won't have one-to-one mappings with surface manifestations in the EHR, so that would require additional work if the value sets change.

Jonathan Perlin – Hospital Corporation of America

Thanks, David. Anybody else or Jim any responses you'd like to offer?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I have a question; this is Dixie, the interface for human consumption of the value sets are they giving any thought to subscription-based delivery versus the UMLS approach of just going to the web and downloading?

Jim Walker – Geisinger Health System – Chief Information Officer

This is Jim, maybe just at this point I can say, you know, thank you to Wes, Chris and Dixie. I will make sure we address those, I don't know if Jacob is on the call and wants to comment on any of those, but I think all of those…we certainly have addressed the CTS-2 SVS issue and, you know, I think Chris is right, we want to consider both of them and have tried to seriously and get them both into the ecosystem as rapidly as possible, but Wes and David's point about the clear division between, you know, managing the value set lifecycle and understanding what it means in terms of implementation for both HIT developers and care delivery organizations, and then Dixie's point about making this more useable are great and we'll try to incorporate those in our work.

Jonathan Perlin – Hospital Corporation of America

Okay, well thank you, Jim, and terrific discussion. Any other points before we move onto next topic.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Jon, this is Doug.

Jonathan Perlin – Hospital Corporation of America

Hey, good morning Doug.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Good morning. Just a question here, there are a series of next steps that are listed with regard to formal governance for value set authority, certainly there is the desire to have standards-based ways of having these pieces fit together, SVS, CTS-2 those sorts of things. What is…are there specific actions that either the Clinical Quality Workgroup is going to take or other activities that the HIT Standards Committee, writ large needs to do that will help get to some of those next steps?

Jonathan Perlin – Hospital Corporation of America

Well, I was hoping you were going in that direction, but it may be useful if you turn it around, unless, Jim or Jamie have some specific thoughts, it may be useful for you to identify what process might be most sort of simpatico.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Well, I certainly believe that in the short-term getting the value sets out there to help support meaningful use are going to be important and an expeditious way to do that I think is going to be very, very helpful for the folks that just need to get access to things. I do think that the CTS-2 standard as it exists is very, very rich, there are a lot of different things that it can do. The question is whether or not there are portions of that that can be sort of simplified or driven forward as a suite of operations, if you will, on value sets. And there is probably some work that needs to be done to make sure that we have multiple ways that are standards-based to be able to share, update, version, curate all those other things around the value sets.

To me, one of the most important things for us to get clarity on is going to be around formalizing the governance and I think that's an area that probably extends beyond just clinical quality, but in fact begins to take on some policy issues, it I think touches on a lot of different things and it may be that we need to…once we get through some of the, you know, the upcoming work on Meaningful Use Stage 2 and setting the stage for Meaningful Use Stage 3, actually convene a group to specifically look at how we would look at governance.

I think it also ties into some of the conversations that we had last month just at the very, very end in which people were saying, what are we going to do to be able to coordinate across, you know, sort of a set of standards that are recognized internationally as the US standards for Health Information Technology and certainly the value sets and the way in which the governance around that has to fit into that, so, there may be some opportunities in the course of the next few months to convene a new group that might be able to explore this explicitly.

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)

This is Becky Kush and I'd like to just second what Doug was just talking about because we've been spending quite a bit of time in the last couple of years looking at the value sets around research and I would hope that they would in some way be used together with what work is happening with the quality value sets and we've been looking at governance around that for quite a while. I'm not sure we have the answer, but we have a lot of work that could contribute to that.

Christopher Chute – Mayo Clinic College of Medicine

And this is Chris; I think we would all warmly welcome that, Doug. I think the advice or the thought is indisputable that we can all benefit from a consolidation/coordination. I did want to, I guess, address one evident misunderstanding and that's the perceived complexity of CTS-2, it's extraordinarily well partitioned, so having what you might consider CTS-2-lite, which is just enough to serve up value sets is already easily identifiable and from a vendor perspective they need not be concerned with all the other capacity.

However, if they start using SVS then there are incompatibilities in terms of REST protocols and the like, and so if they want to extend that in any way we will inevitably be in a situation of inventing extensions to SVS that quite frankly already exist in CTS-2, and that's really the impetus to suggest that we have a cohesive and coherent way of using RESTful interfaces for terminology services access including, of course, simple value set distribution.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David, not that I'm anxious for more work for that NwHIN Power Team, but I wonder if this is something that could be put to the test of our evaluation process.

Christopher Chute – Mayo Clinic College of Medicine

Good suggestion.

Jim Walker – Geisinger Health System – Chief Information Officer

Yeah, great suggestion, David. This is Jim.

Jonathan Perlin – Hospital Corporation of America

I think I've heard a couple of action items out of this and rather than trying to engineer in full detail at this point, Doug, I think your suggestion was very well received to convene a group for further input and I think the second suggestion of applying our recently constructed rubric to, whether it's CTS-2-lite or otherwise sounds like one that was already very well received. Other large thematic comments before we move on?

Jim Walker – Geisinger Health System – Chief Information Officer

Jon, this is Jim, is quickly, I mean, we have projected that the meeting Doug's talking about we just wanted to make sure it was after we had everything done for MU 2 that needed to be done.

Jonathan Perlin – Hospital Corporation of America

Great, any area you'd like to parse out as concerns for MU 2?

Jim Walker – Geisinger Health System – Chief Information Officer

No, I think it was just a matter of keeping the scope simple and making certain we could deliver just simple access to value sets as rapidly as possible for MU 2 work and then, you know, sort of go back and make everything about the system more useable and more efficient.

Jonathan Perlin – Hospital Corporation of America

That sounds like a good way to set the task.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

And, I think to Chris's point, you know, one of our other principles is to take that path of least regret and so I think it is important for us to think long-term as well as how we would be able to support governance and how we'd be able to support the sharing of these value sets under this rubric of sort of the governance process.

Jim Walker – Geisinger Health System – Chief Information Officer

Oh, and this is Jim, just in case I was misunderstood, I think David's suggestion that we use the new methodology for evaluating standards, I think that could be very useful as soon as it was feasible.

Jonathan Perlin – Hospital Corporation of America

Very good, then I think we have a work plan to go forward. Jim, anything else you'd like to add to this conversation?

Jim Walker – Geisinger Health System – Chief Information Officer

No, thanks a lot, Jon.

Jonathan Perlin – Hospital Corporation of America

Appreciate your work, thank you and the workgroup. And let me turn back to John Halamka perhaps any introductory comments into Doug's ONC update?

John Halamka – Harvard Medical School

Great, well, thanks very much. As we all recognize, at the end of aura, the aura error is ending shortly and this means reduction in discretionary funds that might be available for a variety of tasks related to HIT including the S&I framework and that as we discussed in the last meeting it was important to the Standards Committee, recognizing that resources are going to be somewhat constrained, to be able to have insight into what projects are in process, what projects are proposed, trying to make sure that we use our resources and time to the greatest extent possible to support Meaningful Use Stage 2 and 3, and that as an advisory committee that we wished a role.

And, so today we are going to continue that discussion from our previous meetings. We did not really get to the question and answers for Doug about current projects, projects that have been discontinued or projects that need our assistance, as well, to the extent that Doug can comment on any of the testing and certification activities, recognizing that we are in this somewhat awkward period where the final rule has not yet been issued and there is still much work in process going on regarding testing and certification criteria, but knowing that we must, in support of the industry and providers, get timing…get the testing and certification final materials out in a rapid fashion. Certainly anything Doug could suggest or offer would be helpful to us all. So, Doug, happy to turn it over to you as we being the Q&A on S&I and the future of the activities in a budget constrained environment.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Sure, so thank you very much. I did not prepare any additional slides, because basically this is a follow-on to the conversations that we began at the last meeting. There have been a few things that have come…have happened since then, I just want to update people on that just to give a sense for what's going on. I also would like to reserve a little bit of time, and this may be a conversation that will be very, very brief, but to talk a little bit about dental vocabularies as well as an issue that has come up, and that I wonder if we want to make sure that we address some of those things, particularly in the light of some of the value set discussions that have gone on.

So, one of the things that I can tell you, is that since the last meeting, in fact at the end of July we posted on eBuy, a new proposal which is called a BPA, and for those not familiar with government-speak, a BPA is a Bulk Purchasing Agreement. What that does is it allows us to create a contractual mechanism with one or many vendors to be able to write task orders to support much of the work that's going on in the standards and interoperability framework.

And so, we will be receiving proposals in the course of the next couple of weeks, evaluating those and our intention is going from here is that that will serve as a mechanism for us to continue supporting the standards interoperability framework in the post-era environment.

So, we have been putting into place, this has been under development really for the last few months, and we're putting into place the mechanism that will allow us to be responsive to the needs that we have to accelerate the standards process. This particular way of funding the S&I framework allows us to be very specific about what the deliverable is, it allows us to do this in a much more rapid and iterative fashion. And so, we're really grateful that our office of mission support and others have been able to sort of get this out on the streets and we'll use that as sort of the operational arm to get things moving. So, we are putting into place those pieces that we need to do to be able to continue the funding.

As you know, under the Bennett Amendment, I'm sure all of you have been reading that with great interest, but the Bennett Amendment that was passed a number of months ago says that we have to make sure that ARRA funding is, the period of performance for those things ends in September 2013 and the obligations along ARRA funding are finished around December 2012. So, we have been looking at the contracts that we have currently in place. We are trying to work very closely with the participants there to finish up the work that is currently underway and then to be able to transition to this new vehicle that we'll be able to continue the work of the S&I framework.

I think the other thing to note is that testing and certification remain an important aspect of our portfolio of getting people to interoperability. I think we talked about it last month is that, you know, a standard will get you maybe 60% of the way there. A good implementation guide might get you 75% of the way there towards interoperability, but ultimately the way in which we understand how computer systems can interoperate is really through getting them out there, getting them piloted, and getting them sort of tested.

I think one of the things that we would like to do, and this goes to Farzad's point that he expressed earlier about getting a running start on things, we really would like to make sure that the vendor community and others have opportunities to sort of take a look at the implementation guides and the testing strategies and provide input well before we have all of the other pieces in place. If we want to give people 18 months, it's actually better if we can give them longer than that, because they've been involved in the process both in terms of setting up what is a good standard, what is a good way to implement it and what is a good way to test that people are doing that correctly?

And, so, we have been putting in place plans to develop essentially a support platform that helps us tie the communities that are implementing and coming up with, you know, challenges to that implementation or clarifications that we need with our implementation guides and creating a platform that allows people to share their learning, be able to tie back to our implementation guides into our testing infrastructures. So, part of that is work that we're probably in the next, I don't know, month or so we'll be able to present more clearly what our vision is for that.

But the idea here is maybe we need to start changing around the paradigm. Right now we needed to get the initial building blocks constructed and now we've got a starter set, but what we'd really like to be able to do is to have people who are trying to solve problems related to meaningful use or they're trying to exchange healthcare information, they have a place where they can share those experiences with implementation and some of the challenges that we've had and where there is a gap in the standards or where there is a gap in our clarity around the implementation guides, that we can then use that to drive our standards development processes and to make sure that we get clarity around the implementation guides.

Our Arch type for that has been, in some sense, the Direct Project and, you know, we have had a number of organizations and communities that have implemented that and we realize that one of the things in our implementation guide that talked about certificate discovery needed to be clarified, because we had optionality in there that wasn't going to get us the interoperable solution. And so, then we went back and we updated the implementation guide and provided some additional clarity there within the community.

That's really the direction that we'd like to go and finding a way to have that shared learning so that what comes out is not a series of one-off solutions or small connect-a-thon approaches to sort of having everybody create those bilateral directions, but to using those kinds of connections and using those kinds of experiences to develop robust testing and implementation support so that when we get to the next round with Meaningful Use Stage 3 and the like we actually have set the stage for making sure that those problems are solved and that the outcome of a, you know, this implementation and testing is robust criteria that we can then work with NIST and others to get it into finishing school and to get it into kind of a robust and scalable architecture.

So, with that, I'm going to sort of…that's sort of the update of what are the things that are currently in process and how we're going to continue much of the work. I'm happy to answer specific questions about either initiatives or some of the challenges that we have going forward.

John Halamka – Harvard Medical School

And, Liz Johnson, you can imagine that the Implementation Workgroup, which keeps a pulse on the reality of actually getting products in active use, would be able to provide some valuable input as Doug has described for those things that have optionality that's too vague, I mean, as Dixie pointed out optionality isn't necessarily bad, but if optionality isn't appropriate or is causing interoperability challenges I bet the Implementation Workgroup members are going to hear about it and can offer valuable advice.

Elizabeth Johnson – Tenet Healthcare Corporation – Vice President, Applied Clinical Informatics

Yes, I concur completely, this is Liz, and I think, you know, as Doug has indicated this is the time that we need to truly turn up that sort of communication with those groups and as Walter suggested earlier, you know, to really look at, you know, the beginning of next year, how are people dealing with these challenges and how can we better prepare them for the future.

John Halamka – Harvard Medical School

Well, thank you, and so Doug I know you wanted an open dialog and so let us…given that we've short changed you on time in the past, open up to the Standards Committee for comments and questions to Doug about the S&I framework, testing and certification, and the work that is going on at ONC on the standards front.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David, I have a question.

John Halamka – Harvard Medical School

Please, go ahead.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Doug, as you know, there are a number of…well let me back up a little bit, something like the CCDA is still something of a moving target in that despite the, you know, best efforts of the S&I framework there is still some ambiguities, it was recently re-balloted by HL7 which may be clarified a few, but perhaps opened some new questions and so there a number of efforts in the private sector or quasi-public/private interface sector outside the S&I framework that are working on defining certification tests with an eye towards eventually something that's more plug-and-play than our current interface world. So, the New York State led interoperability Workgroup, the newly renamed HealtheWay Consortium, I think there are probably some others that may surface soon. What's the right approach to ensure that we don't end up with, you know, half a dozen quasi-official definitions of plug-and-play certification standards? How can we avoid that scenario? Does that make sense as a question?

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Yes, it does. So, let me see if I can make sense of an answer. I think the first thing to say is that the only standards that you do not need to update or maintain over time are standards that you never use. And I think what that says is that standards that are important and that people are using will likely have a continued evolution and refinement as we learn better how to manage them and take care of them. So, the notion that CCDA is a moving target in some sense is a good thing in that people are interested in making it better and that's how this iterative and incremental process needs to occur.

But, I take your point about lots of people who are trying to develop solutions in the private sector and other areas to be able to help support that work and I think you all probably remember from last year that there were efforts done in New York at the same time that there were efforts going on to create the consolidated CDA, there was something that was constructed called the constrained CDA that was not exactly the same as a consolidated CDA and we did have to spend some time within both the S&I framework and with ONC to sort of bring those two different things together.

I think part of the challenge is if we can provide support for communities to be able to share best practices or to be able to share what's working and what's not, we're not going to be able to eliminate it, but maybe we can help to focus some of that attention so that we don't get a lot of one-off solutions but in fact what we get is we get a solution that is built upon somebody else's good work that somebody else then can leverage and improve as they go forward as well.

And, so that's part of what we're trying to…you know when we think about the sort of implementation support and testing the way I sort of envision that is that currently in an S&I framework we set up a target and a goal, we create kind of the policy guardrails about how to get to that goal and we define what success looks like without defining what the solution is and at the end of the day we get a building block be it a specification in a consolidated CDA or a transport mechanism within Direct or something that will help us with modular web services. What I envision is that people are going to have to put those building blocks together and what comes out of that is going to be sort of the solution that says if you use LOINC plus HL7 2.5.1, plus Direct, plus an X 509 certificate you can actually securely transport laboratory results between different systems.

But that community to come together about how to assemble those building blocks you'd like to have that come out with kind of an implementation or a solution that says here's how you would put them together and one would hope also a way of validating or testing that somebody is doing that correctly and provide the tools and the resources, and the infrastructure.

I think as we look to 2013 and 2014 I would love for us to be able to leverage these private sector efforts, but to do it in a way that doesn't create a multitude of one-offs but a community of folks that are all learning from each other and driving that towards a common understanding of how to solve the problems.

John Halamka – Harvard Medical School

Other comments? Questions?

Arien Malec – RelayHealth Clinical Solutions

This is Arien.

John Halamka – Harvard Medical School

Yes, Arien, go ahead.

Arien Malec – RelayHealth Clinical Solutions

Just a factual question, in the purchase that you just put out, given the need to do ongoing maintenance of certification criteria and support Stage 3, how many S&I, how many Direct-like or consolidated CDA-like S&I initiatives could you fund in addition and we talked about last meeting about the need for a portfolio management program or process. What's the "N" of the investment that we have to allocate over a portfolio?

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Well, I think a lot will depend on budgets and priorities and what is going to be important to getting us to success. The BPA is a flexible mechanism that will allow us to…depending on resources be able to fund, you know, one too many S&I framework initiatives. From my perspective, I think what is the most valuable is to create some focus around those things that people say or indicate are critical to their ability to sort of meet the objectives of meaningful use and to provide a kind of standards-based interoperable infrastructure.

So, to that end, what you'd really like to do, again kind of focusing on that implementation piece you would like to be working on the things that people care about that they have to do anyway, but that we might be able to provide a mechanism that will accelerate it and that will provide some consensus among the various groups. So, we've got a lot of initiatives out there right now. We need to be able to focus on those things that are going to be critical for both Stage 2 and Stage 3, and I think will require some direction from both the Policy and the Standards Committee to try to figure out what are those critical pieces that we need to focus on and then make sure that we have the resources and the commitment that will get us to success.

Arien Malec – RelayHealth Clinical Solutions

You've in effect got a mechanism for paying somebody but no budget as of yet.

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Well, we have a budget, but what we've provided is sort of a flexible mechanism that can expand as needed to support the activity.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

This is Farzad, Arien, the president's budget for FY13 has included an increase in ONC's, a modest increase, in ONC's level of funding from about 61 to about 66 million much of which would go towards increased appropriated support versus HITECH or ARRA support for the standards activities. We don't have a budget for FY13 as yet. So, where we end up on that is going to influence the depth and breadth of the standards related activities that we can directly support.

I think what this raises is the need to look at the different levels of support that we can potentially offer to various S&I initiatives and maximizing the opportunity for others in this, you know, large industry that is increasingly clamoring for useable standards to be able to contribute their own resources and volunteer activities and so forth to greater extent to compensate for that.

So, you know, I think we are going to need to consider kind of a, to use an Olympic metaphor, bronze, silver and gold level of support for the various S&I initiatives and I think the scaling that will have to happen will be both in terms of a number of initiatives but also in terms of the type of or intensity of support that we can offer, but ideally that would be that counterbalanced by an increased contribution from the participants in the process.

John Halamka – Harvard Medical School

So, certainly as we look at those Meaningful Use Stage 3 proposed criteria what we see are standards gaps and we thought about the appropriate uses of the S&I framework versus the HIT Standards Committee, versus SDOs in the assignment of certain tasks to accelerate a standards maturity and I think, you know, I think, Doug, you know, what you're saying and Farzad what you're saying is that once we see what your budget is and we see what the gaps are then we can assign tasks to the appropriate entity whether that is in the public or private sector with a focus on getting the standards necessary for Meaningful Use Stage 3 as mature as possible, as quickly as possible.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

The other…just putting a final point on it, it may not necessarily be whether the task goes to the Standards Committee or an SDO, or the S&I framework, it may be the relative levels of contribution within an S&I Framework of private sector versus publically funded contract or other support. We did an S&I framework initiative.

John Halamka – Harvard Medical School

Back in the HITSP days, we did have an example, I mean Becky Kush you remember this one, where there were issues that federal dollar were fixed but aspirations in the community were significant and that there was a significant private contribution to accelerate some standards harmonization activities for a particular segment of industry and it worked.

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)

I do remember that one John, thank you.

John Halamka – Harvard Medical School

Yes. Okay, well Arien, any other comments you have? Okay, well other questions for Doug and Farzad on S&I standards, testing and certification criteria?

Wes Rishel – Gartner, Incorporated

This is Wes.

John Halamka – Harvard Medical School

Yes, Wes, go ahead.

Wes Rishel – Gartner, Incorporated

I wanted to pick up on a word in Farzad's comment which was the industry is clamoring, because I think it's accurate. As I listen, as I monitor list servers and so forth, I see an attention among developers in the HL7 structured document community, which is where CCDA comes from, that are far more focused on making the standards work out-of-the-box or as close to possible in implementation not that everyone hasn't always held that as a goal, but for many people the primary thought sort of ended with producing the standard or hardening the standard through an industry event like a connect-a-thon which although valuable, doesn't necessarily produce sufficient hardening to produce the best ratio of implementation cost to value in the real world, it's better than having nothing, but it's not as good as it could be.

And, much more of an interest in these implementers in finding ways to collaborate and I think that it would be appropriate for ONC to look for ways of enabling somewhat ad hoc approaches, I think we have probably multiple levels of support that can be provided, the simplest is a form and there are other forms now such as list servers and so forth that probably serve well enough for that.

The second is what you might call a curated forum where all of the ideas that sort of passed through the channel over the course of a multi-day thread aren't left to word searches of archives of messages but are somehow organized and curated.

The third is, if you will, a mechanism to enable ad hoc multiparty testing using ad hoc testing data, a place to meet, a place to make repositories of testing data perhaps a tool to verifiably de-identify testing data in a way that's consisting but still most of the collaboration that goes on is ad hoc and the value shows up implicitly as implementations go on downstream and then the fourth level would be some sort of consensus process on interpretations of the standard, the applicability of test data, and stuff like that.

That fourth level has a heavy process cost and it sounds roughly on the same order of what we've seen in the S&I framework so far. I think the ground is much more fertile now for actual progress through the lower level supporting of collaboration then it has ever been before. I think it is really the experience of implementing Meaningful Use 1 and having, you know, implementation matter in a way that was never so clearly brought forth or forward that has prepared the ground and this would be a good time to be looking at multiple levels of support in enabling industry going forward.

John Halamka – Harvard Medical School

Well, thank you, and Doug, any comments to that?

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

No, I think I would just sort of echo Wes's comment that I think there is an opportunity here given the work that has gone on in the industry around Meaningful Use Stage 1 to continue to support and convene those communities. I think, one of the things that I hope to be able to get to, and again, it's one of those things that we need to have everybody at the table to help us think this through, is that there is value in developing standards, there is value to implementing and piloting, there is value to kind of using connect-a-thons to help us understand how things work.

But, I think when we're talking about 1800 certified products or we're trying to get these products certified and put out there in a way that allows us to have a scalable approach to achieving interoperability, connect-a-thons can help inform how we should develop our certification criteria and our testing data, but it probably would be a challenging approach to have 1800 different products all trying to figure out how to do those connect-a-thons and so if what we can do is create a robust testing certification approach that allows, you know, we've talked about this before, this notion of a sort of transited property of interoperability that if A can demonstrate interoperability to a reference and that B can demonstrate interoperability to a reference whether the certification criteria or some testing infrastructure, then we have a pretty good sense that A should be able to interoperate with B and that's I think what the gold state would be, it's going to take a lot of work for us to get there and having everybody at the table to be able to support getting to that approach I think is very, very helpful.

We've even talked about, you know, people that have used Skype, you take…Skype has a series of technical pieces that you install on your MAC or you install on your PC and you have to make sure that you've got it configured right for the microphone and for the speakers, and you've got to make sure that it's been installed correctly, but eventually what you want to do is you do a Skype test-call that says, have I done everything right that will allow me to connect to this network of folks that are using the Skype protocol. It would be nice if you had that kind of simplicity in the way in which we support interoperability. Now, that may be aspirational to some degree right now, but that certainly is a gold state that we'd like to strive for.

John Halamka – Harvard Medical School

And, so can you imagine that as we go forward with the formal finalized certification processes that, hey part of the tooling that we develop over time is a test-call for the transmission over the NwHIN of a continuity of care or consolidated CDA document.

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator

So, John, this is Judy Murphy. I have my hand up?

John Halamka – Harvard Medical School

Yes, please.

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator

So, I want to take off on Wes's comments as well and, you know, this is the world that I sit in any way is implementation and so I take these kinds of things really seriously and Wes I really appreciate your comment because I think it does make a lot of sense that we start to not only think about standards development but to actually think about standards implementation and how do we go to the next level of making sure that we're providing the kind of guidance on the implementation that we provide on the development.

So, to that end we've been thinking a lot here, at ONC, about Stage 2 interoperability standards that are probably going to be known in the not too distant future, right? And how do we make sure that folks can implement those? So, part of that is of course understanding the standard itself and that would be the implementation guide, the technical specifications of that.

But, when we think about actually putting it in, in a provider organization whether that's a hospital or a clinic, it's harder than that, right? It's not just understanding the standard; it's understanding the policies within which you're going to interoperate with whoever you're interoperating with. And, it's, you know, what kind of agreements do you make and what about all the other things other than the standards?

And, so interestingly, we thought about that related to healthit.gov and how we're trying to make that a really go to place with really helpful tools and I know that one of the last times that I talked to the Standards Committee I talked about that and I think we're in the throes of moving all of your materials there so hopefully you'll become really familiar with that website.

But, one of the things we're going to be doing for Stage 2 is creating what we're calling for the moment, and the term may change, an implementation toolkit for the interoperability standards and this is work with Doug's team along with using our health information exchange grantees to really look at what's needed, what have we learned and how can we put together a real tangible toolkit that talks about A through Z what do I need to implement. So, not just the standards piece but the people and the process, and the policy pieces, and so I'm hoping that folks are going to find that really interesting.

As I've also mentioned to the Implementation Workgroup, as well as the Standards Committee before, you know, we're looking at taking what used to be just Health Information Technology Resource Center the HITRC stuff and moving that to healthit.gov so in that process we're also looking at what's there and what's not there, and this is one of those things that we thought would be really helpful and informative to those folks that are trying to step up their ability to implement Stage 2 in a timely fashion.

Farzad Mostashari – Health and Human Services – Office of the National Coordinator for Health Information Technology

And to just complete the trifecta here, it's Farzad, I also want to add that we can't do this all using, you know, federal dollars and we would…this is where that, whether it's the testing tools, whether it's the receiver of the Skype call or whatever need not all be built by ONC and giving an opportunity for the community, for vendors and others to be able to contribute to that process and our role potentially becomes, over time, becomes more that of validation rather than creation.

Wes Rishel – Gartner, Incorporated

Wes, I've got my card up, again.

John Halamka – Harvard Medical School

Please, go ahead, Wes.

Wes Rishel – Gartner, Incorporated

Okay, so, first of all I think that paying attention to everything but the standard and the certification of the standard is going to be an enormous contribution and will make huge differences not only in the actual implementation of specified standards but in everyone's understanding the implications of proposed standards much more so than has been the case before. I would like to suggest you take a look as a model at least to a process that WEDI has had for many years which is called the process of creating an implementation timeline, essentially it creates a user-based consensus project plan for implementing a standard, so it calls for all of the…identifying the kinds of tasks that Judy has been talking about in a consensus format among users. And, I would say it also tends to go beyond the areas that Judy identified to look at the planning steps that are associated with operational changes associated with the standard, does putting this standard in effect create a workflow change in the workflow of the organization? So, what are the implications in terms of training the workforce to do it in terms of cross departmental agreement and changes in workflow and so forth?

And, then that work plan is then used as a template for assigning times to meeting fixed deadlines. Stanley Nachimson formally of the CMS has been heading the committee that's done that for ICD-10 implementation and I'm sure neither he nor no one on the committee would make the claim that that was the exact template that everyone needed, but certainly everyone who has seen the activity would agree it creates a much more informed process for discussing the implementation and I think we could look at a model like that.

The second point is, as we talk about funding, a lesson we can learn from many standards activities is that much of the funding source has been from vendors and from consultants who make a business supporting the implementation of the standards such as I did for a long time and that makes a lot of sense in that these are the entities that are most directly impacted by the finances. But, I would like to suggest that this is a time where we have enough fairly large institutions, health delivery organizations that are enough concerned about the implementation of standards that they might be able to contribute more in both money and talent, and create a more balanced form in the process, thanks.

John Halamka – Harvard Medical School

Thank you. Other comments? Questions about S&I, budgets, certification and testing? Judy, I certainly like your comments about the healthit.gov and look forward to a test call button eventually being on that site.

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator

Sounds good.

John Halamka – Harvard Medical School

Okay, well a quiet group today. Now, Doug in terms of timing, I recognize again much in play, but do you have a sense as to when you might be able to share with us more details on testing and certification progress, maybe the next meeting in September?

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Yeah, I think that one of the challenges that we have, particularly when it comes to the more detailed about how testing should occur and the various criteria is it's obviously closely tied to the final rule. We'll be able to speak much more about that once we have the final rule out there for people to take a look at and so I think once that occurs there we will be a tremendous amount of work that we'll be embarking on to make sure that we've got community engagement comments and be able to sort of quickly get to the point where we've got robust testing and certification criteria around those standards that are part of the final rule.

John Halamka – Harvard Medical School

Thank you. Now, also speaking about certification, I know at our last meeting there was discussion of the process by which the final certification bodies and testing bodies would be authorized by ONC, because of course they've had their initial review by ANSI and NIST, at this point has ONC authorized any of these bodies?

Doug Fridsma, MD, PhD, FACMI – Office of the National Coordinator – Director Office of Standards & Interoperability

Judy, I don't know if you want to…

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator

I think Carol is on the call; I was actually going to let her do that, Carol?

Carol Bean – Office of the National Coordinator for Health Information Technology – Director, Certification and Testing

I missed the first part, I think John was asking whether any of the accredited certification bodies have been authorized, was that the question?

John Halamka – Harvard Medical School

Correct.

Carol Bean – Office of the National Coordinator for Health Information Technology – Director, Certification and Testing

Not yet. We've been reviewing the applications. There was some paperwork and some other aspects that needed to be, but, again like many things, expect an announcement very, very shortly.

John Halamka – Harvard Medical School

Good, because, yeah we had hoped that the process would proceed expeditiously and if we are looking at an August timeframe for getting some of these folks authorized…and just so I can understand…recognizing there are two sets of bodies there are the certification entities and the testing entities. Does ONC have to authorize just the certification entities or also the testing entities?

Carol Bean – Office of the National Coordinator for Health Information Technology – Director, Certification and Testing

No, ONC or…either or, the answer is that ONC does not need to authorize the testing entities, things will not change, you know, very dramatically for the test labs, they're under…as we move forward with the permanent certification process, at least in terms of testing to the 2011 test criteria or certification criteria, the authorization is of the certification bodies and one of the things, in addition to paperwork, one of the aspects within the permanent certification program is a surveillance plan, and that's one of the things that we need to be able to review, and at least have on hand to be able to discuss with...across the bodies, etcetera, various approaches that have been proposed for surveillance, but that's an aspect that was not present in a formal way in the temporary program that is present in the permanent program.

And so, that's one of the things that will need to be looked at as we begin the permanent program, but that in itself does not impact…that doesn't have to happen, just to be very clear, for the bodies to be authorized, but that is one of the first steps that they need to do to be able actually to act in the program and that's very similar to the way we did it with the temporary program, which was there was some mandatory training that had to take place before they could…even though they were authorized before we could actually let them loose on the world so to speak.

John Halamka – Harvard Medical School

Great, good. Well, Jon Perlin, I think we have exhausted the questions for the folks at ONC. I would just summarize many of the conversations that we've had about the need to go to next steps with applying Dixie's framework that I think we'll be assigning to the Clinical Operations Workgroup and it's Vocabulary Taskforce, the Clinical Quality Workgroup and probably the Implementation Workgroup a review of the document from the Meaningful Use Workgroup of the Policy Committee specifically, asking for standards, maturity, commentary on several of their more aspirational clinical workflow changes recommended for Meaningful Use Stage 3. So, I think, Workgroup Chairs be on the lookout for e-mails from MacKenzie with that document and probably calls that will be scheduled so that we can give, by September 12th, Paul Tang and the Meaningful Use Workgroup, the information that it needs. Back to you, Jon Perlin.

Jonathan Perlin – Hospital Corporation of America

Well, thank you John and well said, indeed appreciate robust discussion during today's call, we waxed philosophical at times but also I think importantly are keeping the ball moving forward and I know that Farzad and the ONC team really are looking to us to keep things moving forward wearing the dual hats reflecting the challenges, but also bringing forward solutions that allow the forward momentum to continue. So, many thanks to everybody for a very thoughtful discussion, very efficient discussion, perhaps a record and with that let me turn back to MacKenzie and Mary Jo to bring in anyone who may want to offer public comments.

Public Comment

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

Yes, thank you, operator would you open the lines for public comment now please?

Rebecca Armendariz – Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Jonathan Perlin – Hospital Corporation of America

While we're awaiting public comment, Mary Jo or MacKenzie I don't know if you want to make any comments about future meetings, we have a few logistics to work out, but maybe the headline is that certainly ONC and John and I will be in touch as soon as we possibly can with finalizations for October and November. MacKenzie, Mary Jo any comments on logistics?

Mary Jo Deering – Senior Policy Advisor – Office of the National Coordinator for Health Information Technology

I'll let MacKenzie dive in because I know she is working on that.

MacKenzie Robertson – Office of the National Coordinator

Sure, this is MacKenzie Robertson, we're actually currently scheduling out for calendar year 2013 as well, so please look out for those appointments coming out, hopefully by the end of this month if not into early September, but there may be a potential reschedule of the November 15th Standards Committee meeting, but we have not decided on the confirmed date yet.

Jonathan Perlin – Hospital Corporation of America

Well, thank you for that. Any public comments in the queue?

Rebecca Armendariz – Altarum Institute

We have a comment from Michael Arrigo.

Michael Arrigo – No World Borders

Hello, this is Michael Arrigo with No World Borders and thank you for the public comment period; I enjoyed hearing the meeting today. Our company in part does cost containment and management solutions for payers and providers, and I'm interested in the pharmacy impacts of some of the quality measures and so on and maybe connecting the dots a little bit. We're very familiar with the quality measures with some upcoming standards like ICD-10 and so forth, but I wondered if ONC has a comment on the National Drug Codes or NDC 11 digit standard, some of the claims therein ways that drug indications can be tied into the quality measures and pay for performance medicine and thank you for hearing my question.

John Halamka – Harvard Medical School

Now, presumably, I mean Jamie any initial comments you would make if you're wearing your hat as the vocabulary taskforce expert?

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

No, I don't think so, because of, you know…in this setting we're really focused on the RxNorm standard.

John Halamka – Harvard Medical School

Right and I would concur that in general what we are doing going forward is focusing on RxNorm with NLM through this mapping service that we've described as a code set repository for the country offering things like NDC mappings but truly RxNorm is the direction we are all heading in.

Michael Arrigo – No World Borders

Can I follow-up?

John Halamka – Harvard Medical School

Other comments?

Rebecca Armendariz – Altarum Institute

We also have a comment from John Travis.

John Travis – Cerner Corporation

Hi, this is John Travis with Cerner, I also serve with Liz on the Implementation Workgroup, one thing I did want to highlight out of the letter that Liz presented that I think since its being taken as kind of an informed artifact, if you will, that's part of the official record of this meeting, I think it did a wonderful job articulating the impact of the timeline we face on a Stage 1 user in 2014 and I just wanted to highlight and underline the impact on that group of folks as we get into 2014 relative to the proposed requirement that we saw in the NPRM about use of a 2014 certified addition, certified EHR and, you know, whatever we can do to make sure those folks are given an equal way to consideration as to the impact of the timeline as to the Stage 2 year one users who seem to get most of the discussion. Thank you.

Jonathan Perlin – Hospital Corporation of America

MacKenzie, any other comments in the queue?

Rebecca Armendariz – Altarum Institute

We have no further comment at this time.

Jonathan Perlin – Hospital Corporation of America

Okay, let me just ask the committee anything else that anyone would like to put on the table? Okay, well then many thanks to each of you for your time and thoughtfulness and attention, robust discussion today. Many thanks, as always, to the terrific staff at ONC, Farzad and team for your great leadership and we look forward to convening next month, until then we stand adjourned. Thank you.

John Halamka – Harvard Medical School

Thank you, everybody.

Wes Rishel – Gartner, Incorporated

Thank you.

MacKenzie Robertson – Office of the National Coordinator

Thanks.

M

Bye.

W

Bye-bye.

Public Comment Received During the Meeting

The point being made that this point about timing being made before is so true. It is being made over and over because it does not seem that the ONC & CMS is really getting the message from the provider community, the vendor community and even their own committees. The move to EHR is good, but the process is complex and time consuming. Please provide a timeframe that can be met....even if Stages are moved or reporting periods are modified. Patient safety in development, implementation, training must be considered in these hurried timelines.